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February 12, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/635818  
For: *COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION  
OF ENDOGENOUS GENES*  
Inventors: Harrington, John J. *et al.*  
Filed: August 5, 2003  
Our Ref. No.: ATX-007CP4DV13CN

Dear Sir:

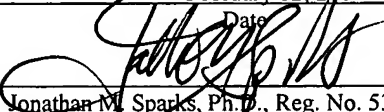
I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08; and
3. A Return Postcard.

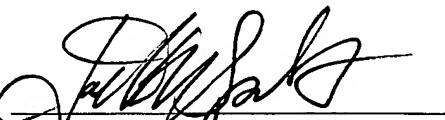
No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

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February 12, 2004

  
Jonathan M. Sparks, Ph.D., Reg. No. 53, 624

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

  
Jonathan M. Sparks, Ph.D.  
Registration No. 53, 624  
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Harrington, John J. *et al.*

Serial No.: 10/635818

Filed: August 5, 2003

For: *COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION OF ENDOGENOUS GENES*

Attorney Docket No.: ATX-007CP4DV13CN

Group Art Unit: 1645

Examiner: Not Assigned

Commissioner for Patents  
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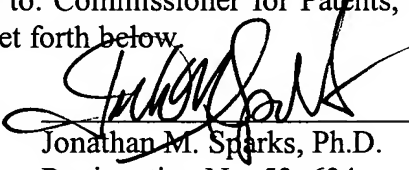
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February 12, 2004

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By:

  
Jonathan M. Sparks, Ph.D.  
Registration No. 53, 624  
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

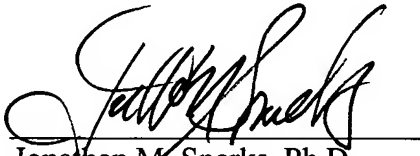
For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. The present application is a Continuation application of U.S. Application No. 09/513,575, filed February 25, 2000 (Attorney Docket No. ATX-007CP4DV13), which is a Divisional application of 09/276,820, filed March 26, 1999 (Attorney Docket No. ATX-007CP4). All references listed on the enclosed PTO Form SB/08 have been previously cited by or

submitted to the Office in the prior applications, and, in accordance with 37 CFR §1.98(d), copies of the references are not enclosed but will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

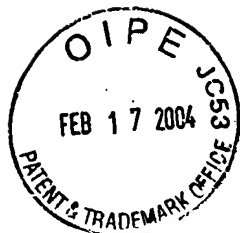


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Date: February 12, 2004

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PTO/SB/08a/b (08-03)

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				Application Number	10/635818
				Filing Date	August 5, 2003
				First Named Inventor	Harrington, John J. <i>et al.</i>
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number	ATX-007CP4DV13CN

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A1	5,024,939	06-18-1991	Gorman	
	A2	5,272,071	12-21-1993	Chappel	
	A3	5,547,933	08-20-1996	Lin	
	A4	5,561,053	10-01-1996	Crowley	
	A5	5,578,461	11-26-1996	Sherwin <i>et al.</i>	
	A6	5,580,734	12-03-1996	Treco <i>et al.</i>	
	A7	5,618,698	04-08-1997	Lin	
	A8	5,621,080	04-15-1997	Lin	
	A9	5,629,159	05-13-1997	Anderson	
	A10	5,641,670	06-24-1997	Treco <i>et al.</i>	
	A11	5,677,170	10-14-1997	Devine <i>et al.</i>	
	A12	5,683,905	11-04-1997	Capon <i>et al.</i>	
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	A14	5,707,830	01-13-1998	Calos	
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	A16	5,733,746	03-31-1998	Treco <i>et al.</i>	
	A17	5,733,761	03-31-1998	Treco <i>et al.</i>	
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	A19	5,789,215	08-04-1998	Berns <i>et al.</i>	
	A20	5,830,698	11-03-1998	Reff <i>et al.</i>	
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	A22	6,136,566	10-24-2000	Lexicon Graphics Inc.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A23	WO 90/14092	11-29-1990	Cell Genesys, Inc.		
	A24	WO 91/01140	02-07-1991	Cell Genesys, Inc.		
	A25	WO 91/06667	05-16-1991	Cell Genesys, Inc.		
	A26	WO 92/19255	11-12-1992	Cell Genesys, Inc.		
	A27	WO 92/20808	11-26-1992	Cell Genesys, Inc.		
	A28	WO 93/09222	05-13-1993	Transkaryotic Therapies, Inc.		
	A29	WO 94/12650	06-09-1994	Transkaryotic Therapies, Inc.		
	A30	AU 71893/94	06-30-1994	*Odile Cohen-Haguenauer		

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				First Named Inventor	Harrington, John J. <i>et al.</i>
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	2	of	7	Attorney Docket Number	ATX-007CP4DV13CN

FOREIGN PATENT DOCUMENTS						
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	B1	FR 2 707 091	01-06-1995	Odile Cohen-Haguenauer		
	B2	WO 95/31560	11-23-1995	Transkaryotic Therapies, Inc.		
	B3	WO 96/04391	02-15-1996	Genentech, Inc.		
	B4	WO 96/29411	09-26-1996	Transkaryotic Therapies, Inc.		
	B5	EP 0 742 285 A1	11-13-1996	Rijksuniversiteit Leiden		
	B6	WO 98/12337	03-26-1998	Chiron Corporation		
	B7	WO 98/14614 A1	04-09-1998	Lexicon Genetics Incorporated		
	B8	WO 99/07389 A1	02-18-1999	Lexicon Genetics Incorporated		
	B9	WO 99/15650 A1	04-01-1999	Athersys, Inc.		
	B10	WO 99/50426	10-07-1999	Lexicon Genetics Incorporated		

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	B11	Auch, D., and Reth, M., "Exon trap cloning: using PCR to rapidly detect and clone exons from genomic DNA fragments," <i>Nucl. Acids Res.</i> 25:6743-6744 (1990).	
	B12	Avoustin, P., <i>et al.</i> , "Non-homologous recombination within the Major Histocompatibility Complex creates a transcribed hybrid sequence," <i>Mammalian Genome</i> 5(12): 771-776 (1994).	
	B13	Barker, C.S., <i>et al.</i> , "Activation of the Prolactin Receptor Gene by Promoter Insertion in a Moloney Murine Leukemia Virus- Induced Rat Thymoma," <i>J. Virol.</i> 66(11):6763-6768 (1992).	
	B14	Black, A.C., <i>et al.</i> , "HTLV-II Rex Binding and Activity Requires an Intact Splice Donor Site and a Specific RNA Secondary Structure," <i>AIDS Res. &amp; Human Retroviruses</i> 5:870 (1992).	
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	C1	Butturini, A., <i>et al.</i> , "Oncogenes in Human Leukemias," <i>Acta Haematologica</i> 78(Suppl. 1):2-10 (1987).		
	C2	Butturini, A., and Gale, R.P., "Oncogenes and Human Leukemias," <i>Intl. J. Cell Cloning</i> 6(1):2-24 (1988).		
	C3	Chakraborty, A.K., <i>et al.</i> , "Transforming function of proto-ras genes depends on heterologous AR 4 promoters and is enhanced by specific point mutations," <i>Proc. Natl. Acad. Sci. USA</i> 55:2217-2221 (1991).		
	C4	Chang, W., <i>et al.</i> , "Enrichment of Insertional Mutants Following Retrovirus Gene Trap Selection," <i>Virol.</i> 193:737-747 (1993).		
	C5	Chow, W.-Y., and Berg, D.E., "Tn5tac1, a derivative of transposon Tn5 that generates conditional mutations," <i>Proc. Natl. Acad. Sci. USA</i> 55:6468-6472 (1988).		
	C6	Church, D.M., <i>et al.</i> , "Isolation of genes from complex sources of mammalian genomic DNA using exon amplification," <i>Nature Genetics</i> 6:98-105 (1994).		
	C7	Crabb, B.S., and Cowman, A.F., "Characterization of promoters and stable transfection by homologous and nonhomologous recombination in <i>Plasmodium falciparum</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 93:7289-7294 (July 1996).		
	C8	Datson, N.A., <i>et al.</i> , "Specific isolation of 3'-terminal exons of human genes by exon trapping," <i>Nucl. Acids Res.</i> 22(20):4148-4153 (1994).		
	C9	Datson, N.A., <i>et al.</i> , "Scanning for genes in large genomic regions: cosmid-based exon trapping of multiple exons in a single product," <i>Nucl. Acids Res.</i> 24:1105-1111 (March 1996).		
	C10	De Benedetti, A., and Rhoads, R.E., "A novel BK virus-based episomal vector for expression of foreign genes in mammalian cells," <i>Nucl. Acids Res.</i> 19:1925-1931 (1991).		
	C11	Dickson, C., <i>et al.</i> , "Tumorigenesis by Mouse Mammary Tumor Virus: Proviral Activation of a Cellular Gene in the Common Integration Region <i>int-2</i> ," <i>Cell</i> 37:529-536 (1984).		
	C12	Dostatni, N., <i>et al.</i> , "Use of Retroviral Vectors for Mapping of Splice Sites in Cottontail Rabbit - Papillomavirus," <i>J. Gen. Virol.</i> 69:3093-3100 (1988).		
	C13	Duesberg, P.H., <i>et al.</i> , "Cancer Genes by Non-Homologous Recombination," In: <u>Boundaries between 7 Promotion and Progression during Carcinogenesis</u> , Sudilovsky, O., <i>et al.</i> , eds., Plenum Press, New York, NY, pp. 197-211 (1991).		
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	C15	Frankel, W., <i>et al.</i> , "Retroviral insertional mutagenesis of a target allele in a heterozygous murine cell line," <i>Proc. Natl. Acad. Sci. USA</i> 82:6600-6604 (1985).		
	C16	Fujisawa, J.-I., <i>et al.</i> , "Functional activation of the long terminal repeat of human T-cell leukemia virus type I by a <i>trans</i> -acting factor," <i>Proc. Natl. Acad. Sci. USA</i> 82:2277-2281 (1985).		

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	D1	Fung, Y.-K.T., <i>et al.</i> , "Activation of the Cellular Oncogene <i>c-erbB</i> by LTR Insertion: Molecular Basis for Induction of Erythroblastosis by Avian Leukosis Virus," <i>Cell</i> 33:357-368 (1983).	
	D2	Goff, S.P., "Gene Isolation by Retroviral Tagging," <i>Meth. Enzymology</i> 152:469-481 (1987).	
	D3	Hay, Bruce A., <i>et al.</i> , "P Element Insertion-Dependent Gene Activation In The Drosophila Eye," <i>Proc. Natl. Acad. Sci. USA</i> , 94:5195-5200 (May 1997)	
	D4	Hayward, W.S., <i>et al.</i> , "Activation of a cellular <i>onc</i> gene by promoter insertion in ALV-induced lymphoid leukosis," <i>Nature</i> 290:475-480 (1981).	
	D5	Jackson, I.J., "A reappraisal of non-consensus mRNA splice sites," <i>Nucl. Acids Res.</i> 19(14):3795-3798 (1991).	
	D6	Joshi, S., "A Putative Approach for Cloning 'Silent' Genes Using Retroviral Vectors," <i>Med. Hypoth.</i> 36:242-245 (1991).	
	D7	Joyner, A.L., "Gene Targeting and Gene Trap Screens Using Embryonic Stem Cells: New Approaches to Mammalian Development," <i>BioEssays</i> 13:649-656 (1991).	
	D8	Junejo, F., <i>et al.</i> , "Sequence analysis of the herpes simplex virus type 1 strain 1704, 1705 and 1706 with respect to their origin and effect on the latency-associated transcript sequence," <i>J. Gen. Virol.</i> 72:2311-2315 (1991).	
	D9	Kaufman. <i>Short Protocols in Molecular Biology</i> , ed. Ausubel <i>et al.</i> John Wiley & Sons, Inc. 1995, pages 16-58-16-60.	
	D10	King, W., <i>et al.</i> , "Insertion Mutagenesis of Embryonal Carcinoma Cells by Retroviruses," <i>Science</i> 228:554-558 (1985).	
	D11	Kreissig, S., <i>et al.</i> , "Expression of peptides encoded by exons in cloned mammalian DNA," <i>Nucl. Acids Res.</i> 24:4358-4359 (November 1996).	
	D12	Lemay, G., and Jolicoeur, P., "Rearrangement of a DNA sequence homologous to a cell-virus junction fragment in several Moloney murine leukemia virus- induced rat thymomas," <i>Proc. Natl. Acad. Sci. USA</i> 81:38-42 (1984).	
	D13	Liang, Y., <i>et al.</i> , "Effects of Alternate RNA Splicing on Glucokinase Isoform Activities in the Pancreatic Islet, Liver, and Pituitary," <i>J. Biol. Chem.</i> 266(11):6999-7007 (1991).	
	D14	Lih, C.-J., <i>et al.</i> , "Rapid identification and isolation of transcriptionally active regions from mouse genomes," <i>Gene</i> 164:289-294 (1995).	
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	D17	Moore, R., <i>et al.</i> , "Sequence, topography and protein coding potential of mouse <i>int-2</i> : a putative oncogene activated by mouse mammary tumour virus," <i>EMBO J.</i> 5(5):919-924 (1986).	

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				Application Number	10/635818
				Filing Date	August 5, 2003
				First Named Inventor	Harrington, John J. <i>et al.</i>
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	5	of	7	Attorney Docket Number	ATX-007CP4DV13CN

NON PATENT LITERATURE DOCUMENTS			
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	E1	Müller, R., and Müller, D., "Co-transfection of normal NIH/3T3 DNA and retroviral LTR sequences: a novel strategy for the detection of potential <i>c-onc</i> genes," <i>EMBO J.</i> 3(5):1121-1127 (1984).	
	E2	Muth, K., <i>et al.</i> "Disruption of Genes Regulated During Hematopoietic Differentiation of Mouse Embryonic Stem Cells," <i>Develop. Dynamics</i> 212:277-283 (June 1998).	
	E3	Neel, B.C., <i>et al.</i> , "Molecular Analysis of the <i>c-myc</i> Locus in Normal Tissue and in Avian Leukosis Virus-Induced Lymphomas," <i>J. Virol.</i> 44(1): 158-166 (1982).	
	E4	Nicolas, J.-F., and Rubenstein, J.L.R., "Retroviral Vectors," In: <i>Vectors: A Survey of Molecular Cloning Vectors and Their Uses</i> , Rodriguez, R.L., <i>et al.</i> , eds., Butterworths Publ., Stoneham, MA, pp. 493-513 (1988).	
	E5	Nilsen, T.W., <i>et al.</i> , " <i>c-erbB</i> Activation in ALV- Induced Erythroblastosis: Novel RNA Processing 15 and Promoter Insertion Result in Expression of an Amino-Truncated EGF Receptor," <i>Cell</i> 41:719-726 (1985).	
	E6	Niwa, H., <i>et al.</i> , "An Efficient Gene-Trap Method Using Poly A Trap Vectors and Characterization of Gene-Trap Events," <i>J. Biochem.</i> 113:343-349 (1993).	
	E7	Nottenburg, C., and Varnus, H.E., "Features of the Chicken <i>c-myc</i> Gene That Influence the 15 Structure of <i>c-myc</i> RNA in Normal Cells and Bursal Lymphomas," <i>Mol. Cell. Biol.</i> 6(8): 2800-2806 (1986).	
	E8	Nouvel, P., "The mammalian genome shaping activity of reverse transcriptase," <i>Genetica</i> 93:191-201 (1994).	
	E9	Nusse, R., "The activation of cellular oncogenes by retroviral insertion," <i>Trends in Genetics</i> 2:244-247 (1986).	
	E10	Nusse, R., and Berns, A., "Cellular Oncogene Activation by Insertion of Retroviral DNA; Genes Identified by Provirus Tagging," In: <i>Cellular Oncogenes Activation</i> , Klein, G., ed., Marcel Dekker, Inc., New York, NY, pp. 95-119 (1988).	
	E11	Payne, G.S., <i>et al.</i> , "Multiple arrangements of viral DNA and an activated host oncogene in bursal lymphomas," <i>Nature</i> 295:209-215 (1982).	
	E12	Peters, G., <i>et al.</i> , "Tumorigenesis by Mouse Mammary Tumor Virus: Evidence for a Common Region for Provirus Integration in Mammary Tumors," <i>Cell</i> 33:369-377 (1983).	
	E13	Petitclerc, D. <i>et al.</i> , "The effect of various introns and transcription terminators on the efficiency of expression vectors in various cultured cell lines and in the mammary gland of transgenic mice," <i>J. Biotechnol.</i> 40:169-178 (1995).	
	E14	Reinhart, T.A., <i>et al.</i> , "RNA Splice Site Utilization by Simian Immunodeficiency Viruses Derived from Sooty Mangabey Monkeys," <i>Virology</i> 224:338-344 (October 1, 1996).	

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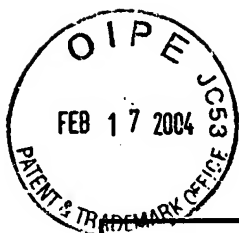
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	F1	Robinson, W.S., "Molecular Events in the Pathogenesis of Hepadnavirus-Associated Hepatocellular Carcinoma," <i>Annu. Rev. Med.</i> 45:297-323 (1994).		
	F2	Salminen, M., <i>et al.</i> , "Efficient Poly A Trap Approach Allows the Capture of Genes Specifically Active in Differentiated Embryonic Stem Cells and in Mouse Embryos," <i>Develop. Dynamics</i> 212:326-333 (June 1998).		
	F3	Segal, D., <i>et al.</i> , "Genetic Transformation of <i>Drosophila</i> Cells in Culture by P Element-Mediated Transposition," <i>Somatic Cell and Mol. Genetics</i> 22 (2):159- 165 (March 1996).		
	F4	Shen-Ong, G.L.C., <i>et al.</i> , "Activation of the <i>c-myb</i> Locus by Viral Insertional Mutagenesis in Plasmacytoid Lymphosarcomas," <i>Science</i> 226:1077-1080 (1984).		
	F5	Shen-Ong, G.L.C., <i>et al.</i> , "Two Modes of <i>c-myb</i> Activation in Virus-Induced Mouse Myeloid Tumors," <i>Mol. Cell. Biol.</i> 6(2):380-392 (1986).		
	F6	Shin, S., and Steffen, D.L., "Frequent activation of the <i>lck</i> gene by promoter insertion and aberrant splicing in murine leukemia virus- induced rat lymphomas," <i>Oncogene</i> 5:141-149 (1993).		
	F7	Simpson, K., <i>et al.</i> , "Stable Episomal Maintenance of Yeast Artificial Chromosomes in Human Cells," <i>Mol. Cell. Biol.</i> 16:5117-5126 (September 1996).		
	F8	Stary, A., and Sarasin, A., "Simian virus 40 (SV40) large T antigen-dependent amplification of an 20 Epstein-Barr virus-SV40 hybrid shuttle vector integrated into the human HeLa cell genome," <i>J. Gen. Virol.</i> 73:1679-1685 (1992).		
	F9	Steffen, D., "Proviral sequences are adjacent to <i>c-myc</i> in some murine leukemia virus-induced lymphomas," <i>Proc. Natl. Acad. Sci. USA</i> 57:2097-2101 (1984).		
	F10	Sun, T.-Q., <i>et al.</i> , "Human artificial episomal chromosomes for cloning large DNA fragments in human cells," <i>Nature Genetics</i> 8:33-41 (1994).		
	F11	Takami, Y., <i>et al.</i> , "Cloning and Characterization of Human Papillomavirus Type 52 From Cervical Carcinoma in Indonesia," <i>Int. J. Cancer</i> 48:516-522 (1991).		
	F12	Tashiro, S., <i>et al.</i> , "Identification of illegitimate recombination hot spot of the retinoic acid receptor alpha gene involved in 15;17 chromosomal translocation of acute promyelocytic leukemia," <i>Oncogene</i> 9:1939-1945 (1994).		
	F13	Tschlis, P.N., <i>et al.</i> , "A common region for proviral DNA integration in MoMuLV- induced rat thymic lymphomas," <i>Nature</i> 302:445-449 (1983).		
	F14	Unger, R.E., <i>et al.</i> , "Simian Immunodeficiency Virus (SIVmac) Exhibits Complex Splicing for <i>tat</i> , <i>rev</i> , and <i>env</i> mRNA," <i>Virology</i> 152:177-185 (1991).		
	F15	van Ooyen, A., and Nusse, R., "Structure and Nucleotide Sequence of the Putative Mammary Oncogene <i>int-1</i> ; Proviral Insertions Leave the Protein-Encoding Domain Intact," <i>Cell</i> 39:233-240 (1984).		

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	G1	Voss, A.K., <i>et al.</i> , "Efficiency Assessment of the Gene Trap Approach," <i>Develop. Dynamics</i> 212:171-180 (June 1998).	
	G2	Westphal, E.M., <i>et al.</i> , "A System for Shuttling 200-kb BAC/PAC Clones into Human Cells: Stable 23 Extrachromosomal Persistence and Long-Term Ectopic Gene Activation," <i>Human Gene Ther.</i> 9:1863-1873 (September 1998).	
	G3	Xiong, J.-W., <i>et al.</i> , "Large-Scale Screening for Developmental Genes in Embryonic Stem Cells and Embryoid Bodies Using Retroviral Entrapment Vectors," <i>Develop. Dynamics</i> 212:131-197 (June 1998).	
	G4	Yoshida, M., <i>et al.</i> , "A New Strategy of Gene Trapping in ES Cells Using 3'RACE," <i>Transgenic Research</i> 4:277-287 (1995).	
	G5	Zhou, H., and Duesberg, P.H., "A retroviral promoter is sufficient to convert proto- <i>src</i> to a transforming gene that is distinct from the <i>src</i> gene of Rous sarcoma virus," <i>Proc. Natl. Acad. Sci. USA</i> 87:9128-9132 (1990).	
	G6	Dialog File 351, Derwent WPI English language abstract for FR 2 707 091.	
	G7	Drug Discovery News, "Lexicon Genetics, Inc.," <i>Genetic Engin. News</i> 19:35 (March 1999).	
	G8	PCT International Search Report as provided by the International Searching Authority.	

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